Service and Facility Specific Policies and Compliance Monitoring
TAC Discussion Summary

ESSHB 1688 Guidance

a) The need for a new and regularly updated set of service and facility specific policies that guide certificate of need decisions [Section 3.2.a], and
b) Mechanisms to monitor ongoing compliance with the assumptions made by facilities that have received either a certificate of need or an exemption to a certificate of need, including those related to volume, the provision of charity care, and access to health services to Medicaid and Medicare beneficiaries as well as underinsured and uninsured members of the community [Section 3.2.f].

Policy Questions

A. CON review should be based on:

1) A state health plan that is updated at least bi-annually by a commission;
2) Detailed criteria, standards and need methodologies, both general and service/facility specific, which are updated at least bi-annually, after consultation with a Technical Advisory Committee;
3) Data from data systems designed to address the specific services and facilities covered such as CHARS counterpart, and others; and
4) Staff analysis followed by public comment process and then final decision by agency designee.

B. The initial steps in the CON analytical process should be:

1) Applications analyzed by CON staff;
2) Public disclosure of analysis, including all data and data sources used to reach analysis, prior to close of public comment;
3) Available resources (including staff) with technical expertise are needed for review; and
4) Quality, access, and utilization data, and licensure information should be obtained from other state agencies as it relates to CON applications/applicants. ~~Advisors will include other state agencies that purchase, fund or regulate~~;
5) Decision will be made by the Secretary of the Department of Health, or designee; and
6) Retain service area definition for use in CON process.

C. In addition to the existing criteria of community need, financial feasibility, structure and process of care, and cost containment, additional factors include:

1) Information related to availability of less costly alternatives;
2) Information related to availability of alternative services;
3) Benchmarking using national criteria for quality, UM, and others;
4) Verification of Medicare/Medicaid accessibility to all residents (as form of population accessibility);
5) Information related to current charity care provision by applicant, as well as projected charity care provision upon completion of project;
6) History of responsiveness/effectiveness of existing providers in surrounding area related to ability and willingness to address need;

7) Consideration for special populations;
8) Potential impact on selected quality indicators for population to be served;
9) Impact on training and education programs;
10) Exceptions or variations for rural (carefully considered and constructed);
11) Information collected during public comment period;
12) Impact on public health and current health system infra-structure , e.g. ~~network adequacy,~~ ability of existing providers and facilities to continue to serve the full community, including underserved and uninsured with a range of services;
13) Service and facility information from licensure, certification, accreditation and other state agencies;
14) ~~Assure level playing field~~ ~~for CON covered services and facilities, i.e., access, consistency of services and quality for consumer;~~
~~15~~ Consistent with state health plan which is based upon evidenced-based medicine or other outcomes measures where applicable/possible;
~~16) Need to prohibit discrimination in provision of services by applicant;~~ and
~~17)~~ 15) Current utilization data/trends that are reviewed and revised based on changes in market and service delivery patterns over time.

D. CON decisions should be made with the following factors in mind:

1) Maintain mechanism for notifying public of Letter of Intent and receipt of application, which may trigger submission of competing applications;
2) Provide Request-for-Proposal invitations for CON proposals based on service needs determined in the State Health Plan;
3) Use plan-driven review cycles which specify certain decision dates and review periods, such as 90-day cycles with decision dates on the 15th of each quarter rather than provider-driven receipt-of-application individual cycles;
4) Batch competing applications for similar service types and geographic areas into the same concurrent review cycles with additional criteria and standards to address differential factors among competing applications; and
5) Use expedited abbreviated cycles for applications which comply with the state health plan and have minimal impact on area health services;
6) Application fees should be established that are sufficient to cover the specific or direct costs of CON application review (not to cover the costs of the timely data system, etc.). Funding sources for other related costs and systems, e.g. data system needs to be identified and provided; and
7) Timely, accountable and reasonable process in compliance with existing statute/rule.

E. CON decisions should be made in a transparent process:

1) Use electronic applications, processing and reporting for public transparency, accountability and public input;
2) Provide for public input after release of staff analysis using written response and public hearing formats allowing for public interaction between applicant and decision-maker;
3) Assure that burden-of-proof is on the applicant to provide documentation of community need and detailed responsiveness to CON criteria and standards;

4) Allow for negotiation prior to final decision in order to adjust project size, cost and scope to accommodate demonstrated needs (needs to occur prior to ex parte or need to reopen for public comment phase);
5) Consistency in review and process is critical, timely and with ~~inter-rater~~ reliability among analysts; and
6) Require transparency of data related to volume, application types, appeals/resolutions, denials, compliance, and others during the phases of pre-analysis by staff, post-analysis by staff, pre-public comment, and post-public comment.

F. CON decisions should be based on state health plan provisions and the ability of the applicant to meet the community need including a process for determining exceptions or "qualifying conditions".

1) Planning-based, analytically-oriented, evidence-based health care criteria and standards which are updated at least bi-annually;
2) Structured to differentiate between competing applications when need is absent to support all appropriate applications;
3) Criteria should be established to permit the review and approval of an application ~~It is permissible for an applicant in a sole provider service area to put forth an application~~ to address a community need absent ~~outside~~ usual CON numerical definition of need, e.g., history of current provider services not acceptable or utilized by community; ~~and~~
4) Established tie-breaking criteria in the situation of "equal" competing applications for a defined need.
5) To assure the safe, appropriate, and cost-effective transfer of new medical technology or services throughout the state, a certificate of need shall not be required for the purchase and operation of research equipment that is to be used in a clinical trial that has received written approval from a duly constituted institutional review board of an accredited school of medicine or other health profession to establish its safety and efficacy, and does not increase the bed complement of the institution in which the equipment is to be located. After the clinical trial has been completed, a certificate of need must be obtained for continued use in such facility or for such service.
6) Assure that similar services are regulated or reviewed which addresses the need of the consumer for quality health services.

G. Conduct post-decision monitoring relative to following factors:

1) Retain current process related to monitoring timeframes;
2) Establish the length of compliance accountability and oversight for at least five years after project completion;
3) Maintain communication between affected state agencies to permit cross-check between licensing, certification, registration and/or reimbursement sources about scope of services in compliance with approved application;
4) Establish and enforce penalties for non-compliance with provisions and conditions of the CON-approved application such as curtailment of services, fines or others;
5) Continue to provide for periodic progress reports after decision until the service becomes operational, then require documentation of completed costs;

6) Applicant is providing the approved service based upon assumptions that led to approval, to population promised, at the promised level of charity care, in compliance with conditions added, observing the ~~appropriate~~ utilization/volume standards ~~as~~ appropriate in tertiary services (or be able to demonstrate that departure from the assumptions is reasonable and has not impacted quality outcomes), and attaining "special conditions/representations" that resulted in the decision to award.

H. ~~Services~~ Systems ~~requiring CON review~~ should be established and/or enhanced to support application analysis and performance monitoring:

1) The data for CON analysis and monitoring should be a subset of a comprehensive data system for state health planning which is a public pathway to improved data collection methodology and reporting consistent with technological advances.
2) There should be ongoing CON data collection acquired and reported by an independent state agency using consistent and reliable performance measures. Data, as it relates to CON reviewable services, should include comprehensive inpatient and outpatient data, financial and utilization information related to charity care, quality, and cost regardless of the service location. Data should be publicly available for applicants and observers to assure transparency within the monitoring system. Data collected in this process may produce indications for quality improvement, performance improvement and other quality of care issues. This should be reported to state planning body and all appropriate agencies whose authority extends to this issue.